

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of severity of pain in continuous Epidural Infusion of Bupivacaine and Fentanyl versus Patient Controlled Analgesia techniques for Labor Analgesia

Protocol summary

Summary

Patient controlled epidural analgesia, is a technique in which, patient can control her analgesic dosage, according to for pain intensity. There are several combined regimes with lower analgesic doses for better and safer control of labor pain. The aim of this study is to find an appropriate analgesic protocol for labor pain. After approval from ethic Committee of Tabriz University and receiving informed consent, 60 pregnant patients candidate for vaginal delivery with lumbar epidural analgesia, will randomly allocate in two groups of 30. An epidural catheter will be inserted for all patients via lumbar epidural technique and patients of two groups will receive primary loading dose of analgesic solution including bupivacaine 0.125% plus fentanyl 3 µg/ml (total volume of 10 ml) from epidural catheter. Patients of group one will receive background infusion of the analgesic solution with the rate of 8 ml/h via infusion pump. In the second group, patients will receive 2 ml of solution with pressing the button, and if needed, 8 ml of the analgesic solution will be administered to them according to the anesthesiologists order. Severity of pain will be evaluated with VAS (Visual Analogue Scale) scoring system 20 minute and then every 1 hour after beginning of analgesia, number and total dose of bupivacaine used during labor and delivery will be assessed and recorded with another person. In all patients upper sensory block limit, depth of motor block will be recorded. Data will be analyzed using SPSS version 17.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121610765N6**
Registration date: **2016-07-08, 1395/04/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-08, 1395/04/18

Registrant information

Name

Sousan Rasooli

Name of organization / entity

Alzahra hospital/Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

rasoolis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research center, Tabriz University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of severity of pain in continuous Epidural Infusion of Bupivacaine and Fentanyl versus Patient Controlled Analgesia techniques for Labor Analgesia

Public title

Comparison of Continuous Epidural Infusion of Bupivacaine and Fentanyl versus Patient Controlled Analgesia techniques for Labor Analgesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Parturients with 18-40 years of old; parturients with ASA Class I or II; consenting to be including to the study; women with active labor and vertex presentation Exclusion criteria: Parturients with ASA Class III or higher; cardiovascular diseases; respiratory diseases; contraindication for epidural ; presentation other than vertex; patients with chronic pain and use of analgesics; diabetics

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Golgasht Ave, Tabriz University of Medical Sciences,

City

Tabriz

Postal code

Approval date

2016-01-18, 1394/10/28

Ethics committee reference number

TBZMED.REC.1394.1046

Health conditions studied

1

Description of health condition studied

Labor pain

ICD-10 code

O80

ICD-10 code description

Single spontaneous delivery

2

Description of health condition studied

delivery

ICD-10 code

O84

ICD-10 code description

Multiple delivery

Primary outcomes

1

Description

pain

Timepoint

every 30 minutes from drug administration until delivery

Method of measurement

visual analog scale

Secondary outcomes

1

Description

motor block

Timepoint

every 30 minute from drug administration to delivery

Method of measurement

Modified Bromage scale

Intervention groups

1

Description

Patients of group one (group receiving continued infusion, 30 patients) will receive the blobs dose of solution that contain bupivacaine 0.125 plus fentanyl 3µg/ml (total volume of 10 ml) through catheter, and they will receive background infusion ml/h 8 of same solution with infusion pump.

Category

Treatment - Drugs

2

Description

Patients of group two (30 patients) will receive the blobs dose of 10 ml from solution that contain bupivacaine 125 mg (26 ml bupivacaine 0.5% and 100 µg fentanyl in 100 ml normal saline through catheter. This group has not background infusion, and patient will receive drugs with

press the button control of pump when need, and anesthesiologist will administer 8 ml of same solution when need to further analgesic.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Elahe Saheb Madarek

Street address

Alzahra Hospital, South Artesh Ave

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for reaserch, Tabriz University of Medical Sciences

Full name of responsible person

Sousan Rasouli

Street address

Vice chancellor for reaserch, No 2, Central bulding of Tabriz University of Medical Sciences, Golgasht Ave

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for reaserch, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Reaserch center, Tabriz University of Medical Sciences

Full name of responsible person

Sousan Rasouli

Position

Professor of Anesthesiology

Other areas of specialty/work**Street address**

Alzahra Hospital, South Artesh Ave

City

Tabriz

Postal code**Phone**

+98 41 3553 9161

Fax

+98 41 3556 6449

Email

Rasooli_s@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Reaserch Center, Tabriz University of Medical Sciences

Full name of responsible person

Sousan Rasouli

Position

Professor of Anesthesiology

Other areas of specialty/work**Street address**

Alzahra Hospital, South Artesh Ave

City

Tabriz

Postal code**Phone**

+98 41 3553 9161

Fax

+98 41 3556 6449

Email

rasooli_s@yahoo.com

Web page address**Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty